IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY, GENEOHM SCIENCES CANADA, INC. and HANDYLAB, INC.,	)	
Plaintiffs,	)	C.A. No. 19-1126 (LPS)
v.	)	
NEUMODX MOLECULAR, INC.,	)	
Defendant.	)	

PLAINTIFFS' BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS NEUMODX MOLECULAR INC.'S AMENDED COUNTERCLAIM FOR INVALIDITY OF THE '708 AND '900 PATENTS

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1	*Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR2019-00490, Paper 1 (P.T.A.B. Dec. 20, 2018)
2	*Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR2019-00488, Paper 1 (P.T.A.B. Dec. 20, 2018)
3	*Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR2019-00488, Paper 15 (P.T.A.B. Aug. 28, 2019)
4	*Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR2019-00490, Paper 15 (P.T.A.B. Aug. 28, 2019)
5	*NeuMoDx Molecular Inc. v. HandyLab, Inc.*, No. IPR2019-01494, Paper 2 (P.T.A.B. Aug. 15, 2019)
6	*NeuMoDx Molecular Inc. v. HandyLab, Inc.*, No. IPR2019-01493, Paper 2 (P.T.A.B. Aug. 15, 2019)
7	*NeuMoDx Molecular Inc. v. HandyLab, Inc.*, No. IPR2019-01493, Paper 8 (P.T.A.B. Feb. 5, 2020)
8	*NeuMoDx Molecular Inc. v. HandyLab, Inc.*, No. IPR2019-01494, Paper 8 (P.T.A.B. Dec. 23, 2019)
9	*Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR2019-00490, Paper 51 (P.T.A.B. July 14, 2020)
10	*Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR2019-00488, Paper 52 (P.T.A.B. July 14, 2020)

I. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs Becton, Dickinson and Company, GeneOhm Science Canada, Inc., and HandyLab, Inc. (together, "BD" or "Plaintiffs") filed this patent infringement action against NeuMoDx on June 18, 2019. D.I. 1. On June 25, 2020, Plaintiffs filed their First Amended and Supplemental Complaint, asserting U.S. Patent Nos. 8,273,308; 8,703,609; 7,998,708; 8,323,900; 8,415,103; 8,709,787; 10,494,663; 10,364,456; 10,443,088; 10,604,788; 10,625,261; 10,625,262; and 10,632,466. D.I. 54.

On December 20, 2018, Qiagen North American Holdings, Inc. ("Qiagen") filed two petitions for *inter partes* review ("IPR") challenging all claims of U.S. Patent Nos. 7,998,708 (the "'708 patent") and 8,323,900 (the "'900 patent"), which the Board instituted. NeuMoDx subsequently filed its own, substantively identical, petitions for IPR; the Board instituted NeuMoDx's IPRs and joined them to Qiagen's IPRs. The Board issued final written decisions upholding the validity of the '708 and '900 patents in July 2020.

NeuMoDx filed its amended answer and counterclaims on December 11, 2020. D.I. 115. As its Second Amended Count, NeuMoDx counterclaims for a declaratory judgment of invalidity of the Asserted Patents, including as to the '708 and '900 patents. NeuMoDx's invalidity counterclaims raise prior art against the '708 and '900 patents that were raised or reasonably could have been raised in the '708 and '900 IPRs. Plaintiffs therefore move to dismiss NeuMoDx's invalidity counterclaims as to the '708 and '900 patents under Federal Rule of Civil Procedure 12(b)(6) on the grounds that they are precluded by statutory estoppel.

II. SUMMARY OF THE ARGUMENT

NeuMoDx's counterclaim for a declaratory judgment of invalidity as to the '708 and '900 patents fails to state a claim upon which relief can be granted because NeuMoDx is estopped from raising the same prior art references it raised or reasonably could have raised in the IPRs it brought against the '708 and '900 patents.

III. BACKGROUND AND STATEMENT OF FACTS

On December 20, 2018, Qiagen North American Holdings, Inc. ("Qiagen") filed two petitions for *inter partes* review ("IPR") challenging all claims of U.S. Patent Nos. 7,998,708 (the "'708 patent") and 8,323,900 (the "'900 patent"). *See* Qiagen's '900 Petition, *Qiagen N. Am. Holdings v. HandyLab, Inc*., No. IPR2019-00490, Paper 1 (P.T.A.B. Dec. 20, 2018) (challenging the '900 patent) (Ex. 1); Qiagen's '708 Petition, *Qiagen N. Am. Holdings v. HandyLab, Inc*., No. IPR2019-00488, Paper 1 (P.T.A.B. Dec. 20, 2018) (challenging the '708 patent) (Ex. 2). Qiagen's updated mandatory notices identified NeuMoDx Molecular, Inc. ("NeuMoDx") "as a real party-in-interest." *See* Petitioner's First Updated Mandatory Notices, *Qiagen N. Am. Holdings v. HandyLab, Inc*., No. IPR2019-00488, Paper 15 at 1 (P.T.A.B. Aug. 28, 2019) (Ex. 3); Petitioner's First Updated Mandatory Notices, *Qiagen N. Am. Holdings v. HandyLab, Inc*., No. IPR2019-00490, Paper 15 at 1 (P.T.A.B. Aug. 28, 2019) (Ex. 4). On July 16, 2019, the Board instituted proceedings in IPR2019-00490 and IPR2019-00488.

On August 15, 2019, two months after this litigation was filed, NeuMoDx filed its own, "substantively identical" petitions for IPR against the '708 and '900 patents, listing Qiagen and Qiagen's corporate parent as real parties-in-interest, and moved to join Qiagen's IPR2019-00490 and IPR2019-00488. *See* Petition, *NeuMoDx Molecular Inc. v. HandyLab, Inc*., No. IPR2019-01494, Paper 2 at 1, 5 (P.T.A.B. Aug. 15, 2019) (challenging the '900 patent and stating, "[t]he current petition is substantively identical to the IPR2019-00490 petition") (Ex. 5); *see also* Petition, *NeuMoDx Molecular Inc. v. HandyLab, Inc*., No. IPR2019-01493, Paper 2 at 1, 5 (P.T.A.B. Aug. 15, 2019) (challenging the '708 patent and stating, "[t]he current petition is substantively identical to the IPR2019-00488 petition") (Ex. 6).

The Board instituted IPR proceedings in NeuMoDx's IPR2019-01493 and IPR2019-01494, and joined them to Qiagen's IPR2019-00490 and IPR2019-00488, respectively. *See NeuMoDx Molecular Inc. v. HandyLab, Inc*., No. IPR2019-01493, Paper 8 at 5 (P.T.A.B. Feb.

5, 2020) (instituting NeuMoDx's "substantively identical" petition and granting joinder to IPR2019-00488) (Ex. 7); *see also NeuMoDx Molecular Inc. v. HandyLab, Inc.*, No. IPR2019-01494, Paper 8 (P.T.A.B. Dec. 23, 2019) (same and granting joinder to IPR2019-00490) (Ex. 8).

On July 14, 2020 the Board issued final written decisions in IPR2019-00488 and IPR2019-01493 (as to the '708 patent); and IPR2019-00490 and IPR2019-01494 (as to the '900 patent), in each decision upholding the patentability of those patents over the prior art raised in those IPRs. *See* '900 Patent Final Written Decision, *Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR2019-00490, Paper 51 at 16 (P.T.A.B. July 14, 2020) (Ex. 9); '708 Patent Final Written Decision, *Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR2019-00488, Paper 52 at 17 (P.T.A.B. July 14, 2020) (Ex. 10).

NeuMoDx's December 11, 2020 Amended Counterclaims (D.I. 115) include counterclaims for declaratory judgment of invalidity of U.S. Patent Nos. 7,998,708 (the "'708 patent") and 8,323,900 (the "'900 patent"). The factual allegations putatively supporting those invalidity counterclaims rely on the same prior art references "raised in" the aforementioned IPR proceedings. As to the validity of the '708 patent, NeuMoDx alleges:

> Based upon NeuMoDx's ongoing investigation, the claims of the '708 patent ***are invalid in view of at least the prior art raised in IPR2019-00488*** filed by Qiagen North American Holdings, Inc. against HandyLab, Inc, including but not limited to Zou I, U.S. Patent No. 6,509,186; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pease, U.S. Patent App. Pub. No. US2004/0151629; Hsieh, U.S. Patent No. 7,122,799; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; and Wilding U.S. Patent Publication No. 2003/0199081. The Patent Trial and Appeals Board ("PTAB") instituted trial on Claims 1-33 in a decision dated July 16, 2019, finding that "Petitioner has established a reasonable likelihood of prevailing with respect to claims 1-6, 9, 10, 18-20, 23-25, 28 and 33 of the '708 patent" and with respect to dependent claims 7, 8, 11-17, 21, 22, 26, 27 and 29.

See D.I. 115 at 34 (emphasis added). And as to the validity of the '900 patent, NeuMoDx alleges:

> Based upon NeuMoDx's ongoing investigation, the claims of the '900 patent

> ***are invalid in view of at least the prior art raised in IPR2019-00490*** filed by Qiagen North American Holdings, Inc. against HandyLab, Inc, including but not limited to Zou I, U.S. Patent No. 6,509,186; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pourahmadi, U.S. Patent App. Pub. US 2002/0055167; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; and Wilding U.S. Patent Publication No. 2003/0199081. The Patent Trial and Appeals Board ("PTAB") instituted trial on Claims 1-22 in a decision dated July 16, 2019, finding that "Petitioner has demonstrated a reasonable likelihood that it will prevail on its challenge to at least one of the claims of the '900 patent."

See D.I. 115 at 34-35 (emphasis added).

IV. ARGUMENT

The Court should dismiss counterclaims that fail to raise a right to relief beyond a speculative level, including because the counterclaim is precluded.[1] NeuMoDx's factual allegations regarding its '708 patent and '900 patent invalidity counterclaims admit that they rely on prior art "raised in IPR2019-00488" and "raised in IPR2019-00490." D.I. 115 at 34-35. The Board's final written decisions in those proceedings—in which NeuMoDx was listed as a real party-in-interest, and to which NeuMoDx's IPR proceedings were joined—have already held that the claims of the '708 patent and '900 patent are not unpatentable over the prior art raised in those proceedings. *See* Ex. 10; Ex. 9.

Thus, even if accepted as true, NeuMoDx's factual allegations are facially insufficient to support plausible bases for relief regarding the invalidity of the '708 and '900 patents. NeuMoDx's pleaded bases are statutorily estopped under § 315(e). In particular, statutory

[1] The Court must dismiss counterclaims that fail to plead sufficient factual content which, if accepted as true, would allow the Court to draw a reasonable inference that the counterclaimant is entitled to the sought-after relief. *See*, *e.g.*, *Idenix Pharm., Inc. v. Gilead Scis., Inc.*, No. 13-cv-1987-LPS-CJB, 2014 WL 4222902, at *6 (D. Del. Aug. 25, 2014) ("[T]he Court determines that Defendants' invalidity-related counterclaims are subject to the requirements of *Twombly* and *Iqbal*."). The Court must also dismiss claims that are precluded by estoppel. *See Walzer v. Muriel, Siebert & Co.*, 221 F. App'x 153, 155 (3d Cir. 2007) (holding that "[a]lthough res judicata and collateral estoppel are affirmative defenses, they may be raised in a motion to dismiss under Fed. R. Civ. P. 12(b)(6)" and dismissing plaintiff's state claims as "precluded by collateral estoppel"); *M & M Stone Co. v. Pennsylvania*, 388 F. App'x 156, 162 (3d Cir. 2010) (affirming district court's ability to "recogniz[e] the existence of other judicial opinions" to allow party "to raise issue preclusion in a motion to dismiss").

estoppel under 35 U.S.C. § 315(e)(2) "prevents inter partes review petitioners from raising arguments in federal court" that were raised or "could have been raised during their IPRs," including "any references that were known to the petitioner or that could reasonably have been discovered." *Parallel Networks Licensing, LLC v. Int'l Bus. Machines Corp.*, 2017 WL 1045912, at *11 (D. Del. Feb. 22, 2017) (Jordan, J.) ("the prior art references (or combinations) a petitioner 'could have raised' includes any references that were known to the petitioner or that could reasonably have been discovered by 'a skilled searcher conducting a diligent search.'" (citations omitted)), *aff'd*, 721 F. App'x 994 (Fed. Cir. 2018); *see also Wasica Fin. GmbH v. Schrader Int'l, Inc.*, 432 F. Supp. 3d 448, 453, 455 (D. Del. 2020) (citing *Parallel Networks*, and estopping defendant from raising references in litigation that were "previously raised" or "reasonably could have been raised" before the Board).

Accordingly, the Court should dismiss NeuMoDx's invalidity counterclaims against the '708 patent and '900 patent as barred by statutory estoppel. *See Walzer*, 221 F. App'x at 155; *M & M Stone*, 388 F. App'x at 162.

V. CONCLUSION

For all of the above reasons, NeuMoDx's invalidity counterclaims as to the '708 patent and '900 patent should be dismissed.

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January 4, 2021

CERTIFICATE OF SERVICE

I hereby certify that on January 4, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 4, 2021, upon the following in the manner indicated:

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